# REACH COMPLIANCE AMONG COMESA FOOTWEAR TANNERS AND SMES

November 2016





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- Educated at the British School of Leather Technology - UK
- Fellow of the Society of Leather Technologists & Chemists (FSLTC)
- President of the Society of Leather Technologists & Chemists 2006 – 2008
- Member of the American Leather Chemists Association (ALCA)
- 38+ Years in the industry – joined as a trainee leather technician in 1977
- >15 years International Project work and consulting in the leather Sector
- 9+ Years as an independent tannery consultant ALC Ltd
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# John Hubbard

- SATRA Technical Manager
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- SATRA Technology Centre (1996 – Present)
- Coal Research Establishment (1990-6)
- BSc (Hons) Colour Chemistry & Dyeing – University of Leeds 1990

# Programme outline

- REACH Introduction
- Requirements for articles and SVHCs
- Annex XVII Restricted Substances
- Testing for Restricted Substances


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# REACH Introduction

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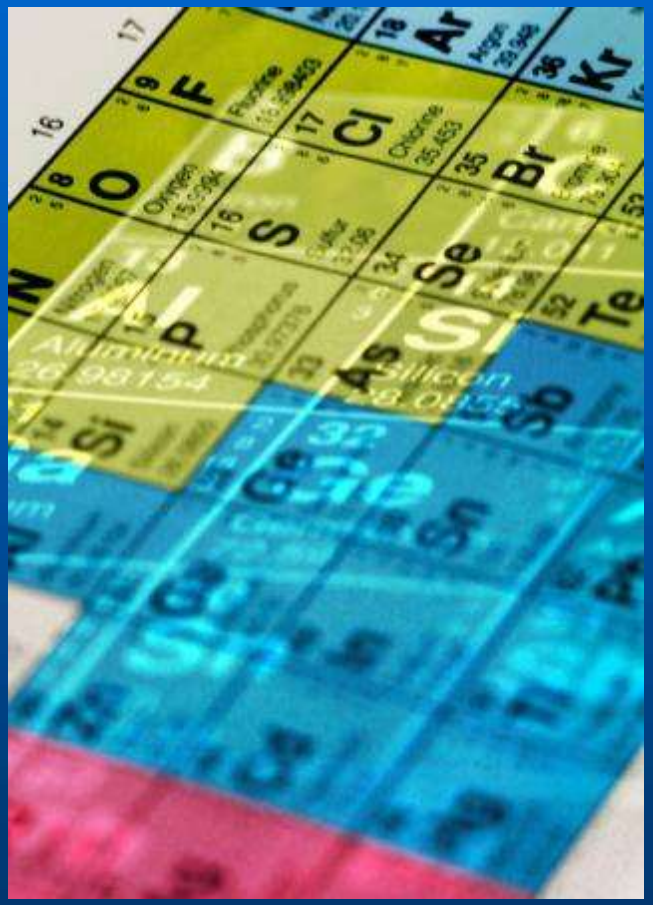
# What is REACH?

- Registration, Evaluation, Authorisation (& restriction) of Chemicals
- Regulation (EC) No 1907/2006
- Entered into force 01 June 2007
- Final phase in dates 2018

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# Why REACH?

- Remove distinction between ‘New’ – post 1981 and Existing chemicals Prior to 1981
- To protect Human Health & Environment
- To impose restrictions on most harmful chemicals
- To improve communication throughout the supply chain

# Who does REACH affect?

- Chemical Manufacturers
- Formulators and Suppliers of Preparations
- Downstream Users
- Suppliers of Articles

# What is covered by REACH?

- All Chemicals supplied in quantities greater than 1 tonne per annum (tpa) into the European Union
- Whether use is industrial, professional or domestic

# Where does REACH apply?

- European Union (EU)
- European Economic Area (EEA):
  *Iceland*
  *Norway*
  *Liechtenstein*

# Requirements for Substances and Preparations

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# Requirements for Substances and Preparations

- Each company supplying each chemical must register
- Registration is per substance not per product
- Must communicate with downstream users
- Authorisation will only cover recognised downstream uses

# Who is responsible for registration?

- Chemical Manufacturer (if in EU)
- Chemical Importer who first brings product into EU (may be multiple organisations)
- Only Representative (Sole agent for manufacturers outside the EU)

# Registration

PHASE IN DATES

<u>Nov 2010</u>

CMR > 1 tpa,

R50/R53 > 100 tpa,

All substances >1000 tpa

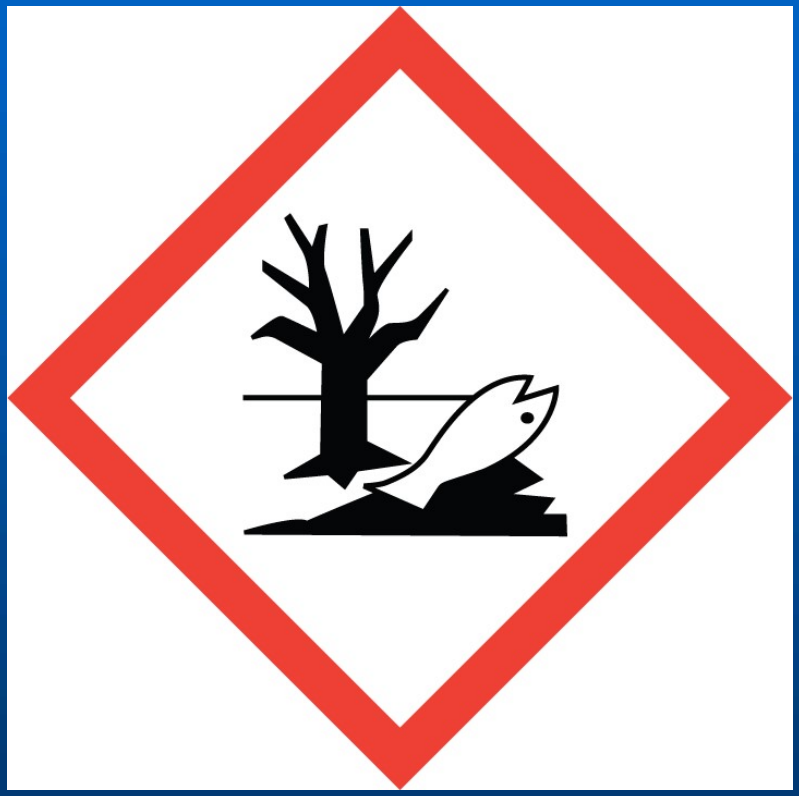
<u>May 2013</u>

100-1000 tpa

<u>Nov 2018</u>

10-100 tpa

1-10 tpa



# Candidate List Substances in Articles

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# Definition of an article in REACH

- “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition”
- Consumer goods will fall into this category
- Liquid products will normally be classified as preparations (mixtures)

# Why Substances in Articles?

- Original proposals only restricted chemical use and production in the EU and had no requirements for product coming into the EU from outside

- Requirements for articles resulted from lobbying by the EU chemical industry

# Candidate List

- Substances of Very High Concern (SVHCs) will be placed in this category during the evaluation process
- Current SVHC list (June 2016) includes 169 Chemicals – ECHA target to complete list by 2020
- Threshold limit 0.1% on **weight of article or separate component**
- Above threshold limit obligations apply

# SVHC Obligations

1. Respond to customer requests within 45 days

2. If one or more SVHC is present above 0.1% but less than 1 tonne of the SVHC is imported per annum – inform supply chain and provide information for safe use of product (or information on exposure prevention)

# Sunset Dates

- 31 SVHCs have been assigned “sunset dates” and added to Annex XIV (the authorisation list)
- As a result, 4 phthalate plasticisers are now banned from use in manufacturing within EU / EEA
- Exemptions can be applied for based on socio-economic benefit
- The authorisation list chemicals will not automatically be restricted in consumer products – this will require additional legislation

# Managing SVHCs

- What materials are used in my products (composition)?
- Are any treatments applied to my product?
- What information does my supplier have about the chemicals used in the product?
- Create a matrix of information and identify any gaps

# Targeted testing for SVHCs and interpreting test results

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# SVHC Testing

- 169 chemicals on the candidate list
- Not practical / economic to test for all 169!
- Not all SVHCs relevant to consumer products
- Some have very specific uses for example in explosives / road surfaces
- Advisable to target testing at those chemicals most likely to be present in your product range

# Efficient Testing

Remember articles which contain substances on the candidate list above 0.1% must provide sufficient information

- 0.1% is a high concentration in analytical terms (1000ppm)
- 0.1% is based on the weight of each component
- Combining similar materials is possible
- Screening testing is an effective testing tool.

# Targeted SVHC Testing

Common screening groups:

- Phthalates on flexible PVCs
- Metal screening using ICP
- Organic Compounds using GC-MS
- Specialist testing where real suspicions exist.

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# Phthalates

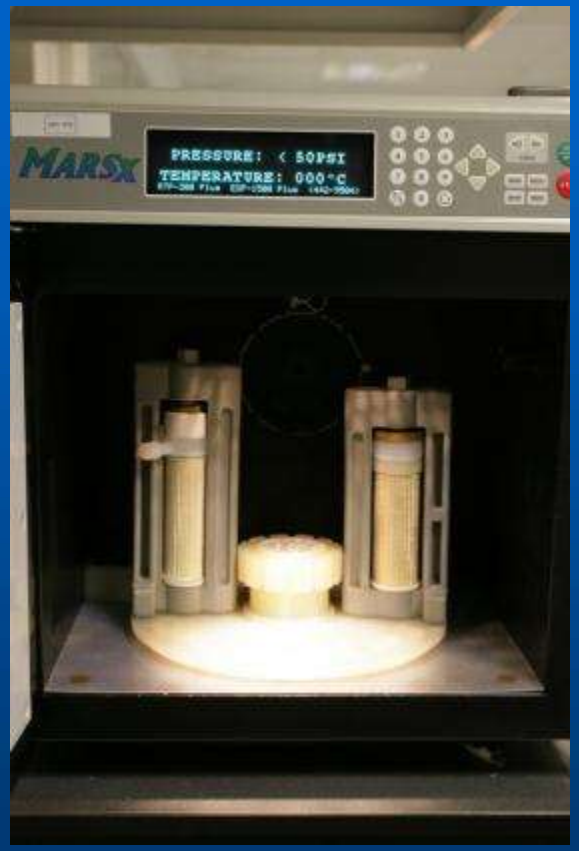
- Esters derived from phthalic acid
- Used to make materials flexible especially PVC
- They may be added in the order of 30-50% by weight to increase the polymer's flexibility
- Not all phthalates are restricted
- Testing - solvent extraction followed by GC-MS

# SVHC Phthalate Plasticisers

| | |
|---|---|
| Benzyl butyl phthalate (BBP) | 85-68-7 |
| Bis (2 ethyl(hexyl) phthalate (DEHP) | 117-81-7 |
| Dibutyl phthalate (DBP) | 84-74-2 |
| Diisobutyl phthalate (DIBP) | 84-69-5 |
| 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP) | 71888-89-6 |
| 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) | 68515-42-4 |
| Bis(2-methoxyethyl) phthalate (DMEP) | 117-82-8 |
| 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear | 84777-06-0 |
| Diisopentylphthalate (DIPP) | 605-50-5 |
| N-pentyl-isopentylphthalate | 776297-69-9 |
| Dipentyl phthalate (DPP) | 131-18-0 |
| Dihexyl Phthalate (DHP or DnHP) | 84-75-3 |
| 1,2-Benzenedicarboxylic acid, dihexyl ester | 68515-50-4 |

# Metal Screening

- High proportion of chemicals on the candidate list contain metals
- These metals can be screened-for using XRF or microwave digestions followed by ICP analysis
- Many of the chemicals contain combinations of metals eg *Lead chromate* contains both lead and chromium



# Metal Screening

## Metals included in the SATRA screening test:

Tin – Sn
Lead – Pb
Cobalt – Co
Chromium – Cr
Arsenic – As
Potassium – K
Zirconium – Zr

Sodium – Na
Boron – B
Zinc – Zn
Strontium – Sr
Barium - Ba
Titanium – Ti
Cadmium – Cd

# GC-MS Screening

- Solvent extraction followed by GC-MS for semi volatile organic compounds
- Used for Anthracene and TCEP screening

# GC-MS Headspace Screening

- GC-MS headspace analysis can be used to screen for volatile organic compounds
- Such as 2-ethoxyethanol,  trichloroethylene and 1,2-dichloroethane
- These may have been used as cleaning solvents, contaminants in adhesives or a specific function e.g. musk xylene is a fragrance

# Specialist testing

- Chromium VI in leathers where high levels of chromium is detected.
- Where water, stain resistant or flame retardant treatments are known to have been added.
- Chloro-alkanes in leather oils.

# The Future?

- Further chemicals to be added to the SVHC List
- SVHCs will become authorised - (Annex XIV)
- Substances may then be added to Annex XVII by further legislative acts
- SIN lists are lobbying documents not proposals

# Annex XVII

Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

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# Key Differences between Candidate List & Annex XVII

- Annex XVII is **mandatory** and all organisations should be able to demonstrate compliance

- Candidate List obligations are not a ban on SVHCs in articles

# Annex XVII

- All requirements of Marketing and Use Directive were incorporated into ANNEX XVII of REACH during May 09.
- Maximum permitted levels are different for each entry and expressed on the material not the article
- Brands / retailers should base their restricted substances list on these requirements
- ANNEX XVII will increase as member states make proposals on SVHC's.

# Annex XVII - Requirements

- Limits based on authorisation to ensure safe use
- May be product, material or process specific
- May prohibit use in the supply chain or residues in final materials

# Annex XVII

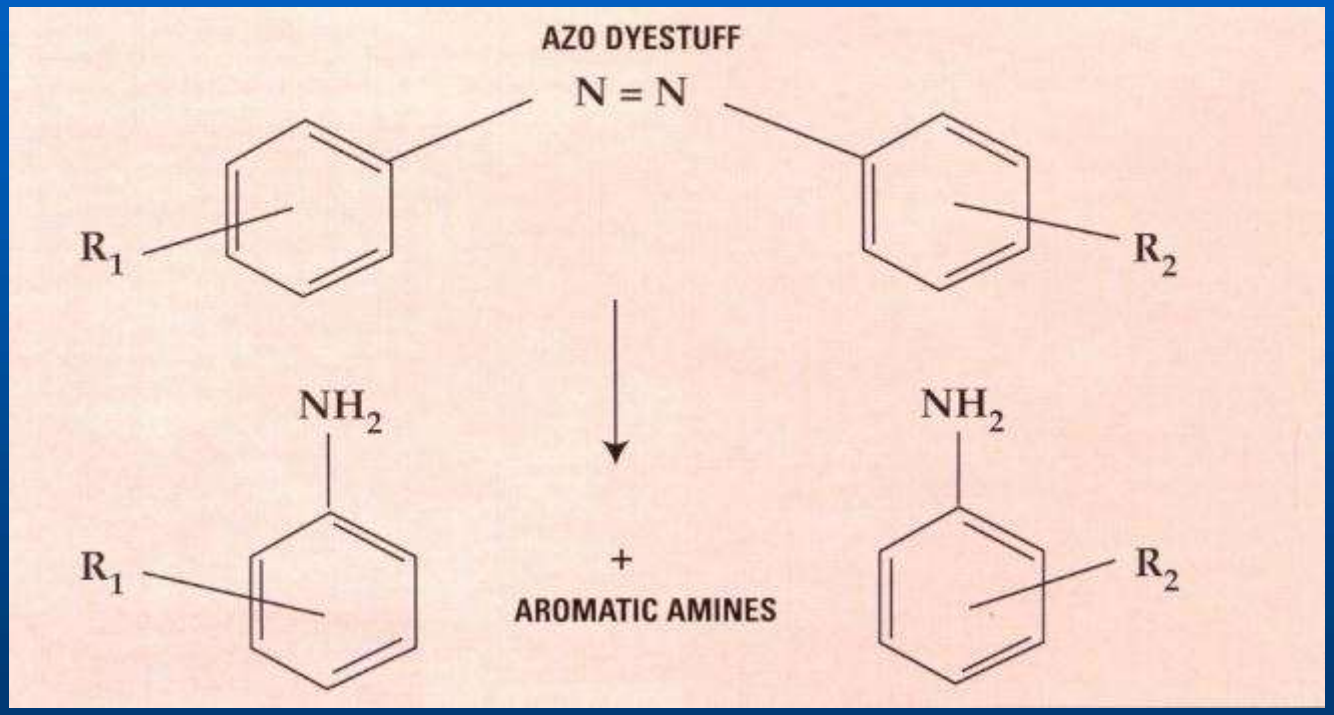
The current revision of annex XVII includes restrictions on 62 unique substances / entries.

https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach

# ANNEX XVII - Key Chemicals in Consumer Products

- Azo dyes
- Pentachlorophenol
- Chromium VI
- Nickel
- Dimethyl fumarate
- Penta/Octa BDE
- NP/NPEO
- PFOS
- Cadmium
- Lead
- Phthalates
- Organotins
- PAHs

# Azo Dyes



# Azo Dyes

- EU restriction introduced in 2002
- 22 restricted Aromatic Amines - **carcinogens**
- REACH Annex XVII entry number 43
- Maximum permitted level 30ppm
- Applicable to dyed leather & textiles in direct and prolonged contact with the skin
- No need to test white or undyed materials or polymers

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# Azo Dyes

- 4-amino bi phenyl
- Benzidine
- 4-chloro-o-toluidine
- 2-Naphthaylamine
- o-aminoazotoluene
- 5-nitro-o-toluidine
- 4-Chloroaniline
- 4-Methoxy-m-phenylenediamine
- 4,4’-methylenedianiline
- 3,3’-dichlorobenzidine
- 3,3’-dimethoxybenzidine
- 3,3’-dimethylbenzidine
- 4,4’-methylenedi-o-toluidine
- 6-methoxy-m-toluidine
- 2-chloroaniline
- 4,4’-oxydianiline
- 4,4’-thiodianiline
- o-toluidine
- 4-methyl-m-phenylenediamine
- 2,4,5-trimethylaniline
- o-anisidine
- 4-aminoazobenezene

# Azo Dyes - Testing

Test methods:

- EN 14362-1

(natural textiles, synthetic textiles)

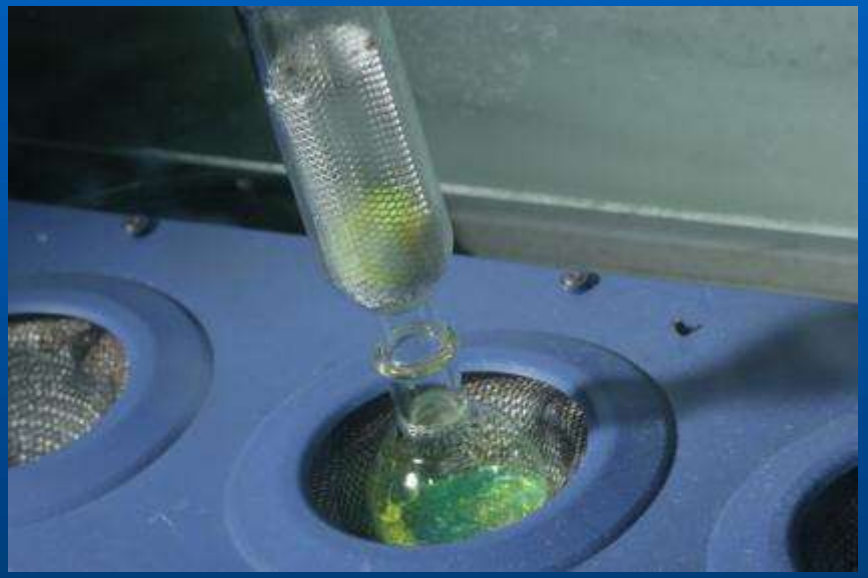
- EN 14362-3

(4-aminoazobenzene)

- ISO 17234-1 (leather)
- ISO 17234-2

(4-aminoazobenzene)

All use GC-MS with HPLC as second confirmatory technique



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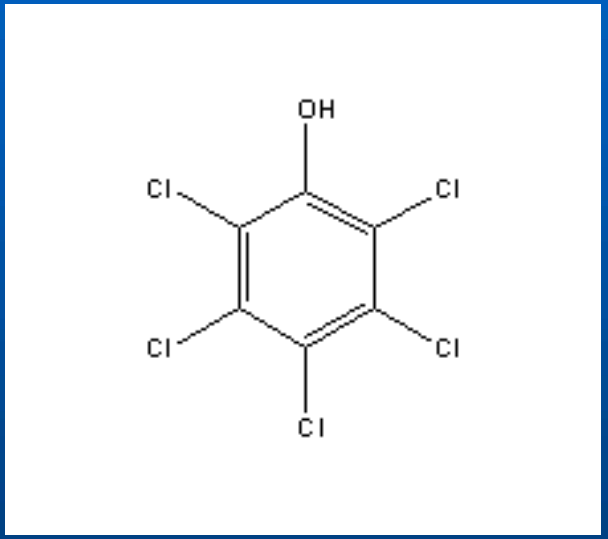
# Pentachlorophenol (PCP)

- Fungicide used historically in leathers and wood
- Fatal if inhaled, toxic if swallowed and toxic in contact with the skin
- Very toxic by inhalation and to aquatic organisms
- Accumulates in the environment
- REACH Annex XVII entry number 22
- Requirement <1000ppm
- Restricted in Germany < 5ppm

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# PCP – Testing

- ISO 17070

(steam distillation extraction)

- SATRA TM 342

(acetone extraction)

# Chromium VI

Might be present in chromium tanned leather as chromium sulphate (Cr III) tanning salts present in low percentage levels

Also called extractable hexavalent chromium (Cr VI)

# Chromium VI

- Skin irritant
- Carcinogen by inhalation & ingestion
- Environmental hazard
- Zero tolerance in German consumer products
- Restricted in toys (EN 71-3, <0.02mg/kg in category III materials)

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# Chromium VI

- Included in innocuousness assessment for protective clothing & gloves containing leather

- Originally Annex XVII entry 47 applied only to cements

- However, Regulation 301/2014 extended entry 47 from 1st May 2015

# Regulation 301/2014

- *5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.*
- *6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of that leather part.*
- *7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.*

# Testing for Chromium VI

- ISO 17075:2007 – extraction in phosphate buffer, UV-Vis detection after reaction with DPC
- Method will shortly be replaced by ISO 17075-1 and ISO 17075-2 (currently at final voting stage)

Key changes:

Cut leather (not ground),

Part 2 uses ion exchange chromatography – fewer interferences

Part 2 will take precident

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# Nickel - Requirements

Extractable Nickel

- Items in prolonged intimate skin contact

< 0.5µg/cm$^2$/week

- Body/Ear piercing posts

< 0.2µg/cm$^2$/week

- Assessment for durability of coatings simulates three years of wear.

# Nickel - Testing

Test methods:

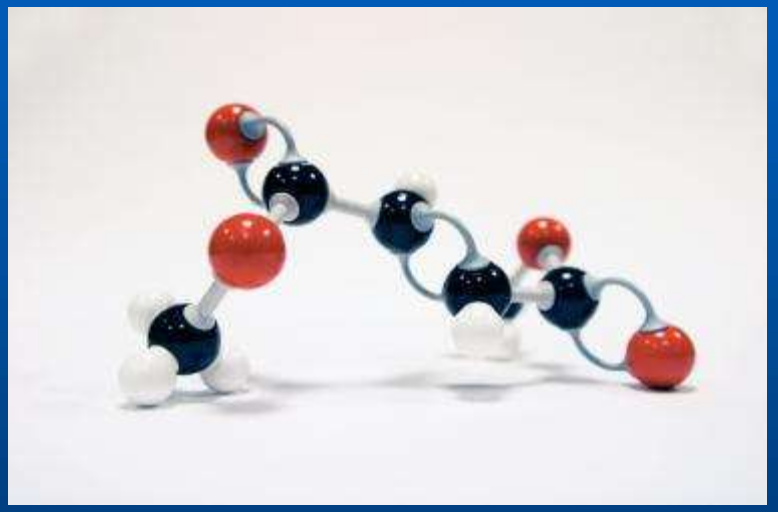
- EN 12472 (wear and corrosion)
- EN 1811 (nickel migration)

If result > 0.28µg/cm$^2$/week could be a fail

- SATRA TM 354 – qualitative spot test for presence of nickel

# Dimethyl fumarate (DMFu)

- Biocide that has been used to control mould growth
- Implicated in contact dermatitis and respiratory problems in furniture and footwear
- Sensitising chemical – adverse reactions at very low concentrations
- Present in packaging as sachets or pouches
- Use was forbidden in Europe (outside Biocidal Products Directive – BPD)



# Dimethyl Fumarate (DMFu)

- Initial emergency ban (2009/251/EC)
- Annex XVII entry number 61 (Regulation 412/2012) – May 2012
- Requirement <0.1 mg/kg in articles
- Test methods:

SATRA DD09/02

pr EN TS 16186

# Alkyl Phenol and Alkyl Phenol Ethoxylates (APE / APEOs)

- Wetting agents and detergents in textiles and leather processes (dyeing)
- Persistent environmental pollutants
- Skin and respiratory irritant
- Nonyl phenol (NP) is toxic to aquatic organisms and is a hormonal substance (endocrine disruptor)

# Alkyl Phenol and Alkyl Phenol Ethoxylates (APE / APEOs)

- Restrictions were introduced on Nonyl phenol and NPE in 2005 on their use within the supply chain
- Maximum allowed limit 1000ppm in mixtures
- 2012 environmental group report highlighted NP and NPEO in many branded products
- Annex XVII Entry number 46 applies to mixtures, however Regulation (EU) No 2016/26 applies from 3rd February 2021

# Regulation (EU) No 2016/26

- NPE restricted to < 0.01% by weight of the textile article or textile part
- Applies to textile articles that can reasonably be expected to be washed during their lifetime
- Definition of textile – at least 80% textile fibres by weight

# Testing for APE & APEOs

EN ISO 18218 parts 1 and 2

- Part 1 – direct Method (using HPLC-MS-MS)
- Part 2 – indirect method (using HPLC-DAD or GC-MS after converting NPE and OPE to NP or OP)

# Cadmium

- REACH Annex XVII entry number 23 (Amended by Regulation 494/2011 and 835/2012)
- 494/2011 extended restriction to a wider range of materials but in dispute by the International Cadmium association (case T456-11)
- Current legal position back to original list of plastics (see next slide)
- Maximum permitted level 100ppm

# Synthetic Organic Polymers where Cadmium must not be used

— polymers or copolymers of vinyl chloride (PVC) [3904 10] [3904 21]

— polyurethane (PUR) [3909 50]

— low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10]

— cellulose acetate (CA) [3912 11]

— cellulose acetate butyrate (CAB) [3912 11]

— epoxy resins [3907 30]

— cross-linked polyethylene (VPE)

— high-impact polystyrene

— polypropylene (PP) [3902 10]

— melamine-formaldehyde (MF) resins [3909 20]

— urea-formaldehyde (UF) resins [3909 10]

— unsaturated polyesters (UP) [3907 91]

— polyethylene terephthalate (PET) [3907 60]

— polybutylene terephthalate (PBT)

— transparent/general-purpose polystyrene [3903 11]

— acrylonitrile methylmethacrylate (AMMA)

# Lead

- Lead is a highly toxic metal
- Children particularly vulnerable
- Like Cadmium can also be used as stabiliser in plastics
- Entry 63 in Annex XVI (as amended by Commission Decision 836/2012 and Regulation 2015/628)
- < 500ppm in jewellery

# Regulation 2015/628

- Restricts the total amount of lead to ≤ 0.05% (500ppm) in accessible parts that may be placed into the mouth by children during normal or foreseeable use.
- Accessible parts defined as having any dimension < 5cm

# Cadmium and Lead testing

- Test method EN 1122 or SATRA TM 443
- Microwave digestion followed by analysis using ICP-OES
- Method can be modified to be used as a screening test for total metals

# Phthalate Plasticisers

Likely to be present in flexible PVC

- Potential carcinogens and endocrine disruptors
- REACH entry numbers 51 and 52 Phthalates in toys and Childcare articles
- Specific restriction to these product groups

Remember phthalates listed on the SVHC list apply to all articles

# Phthalate Plasticisers

Less than 0.1% in toys and childcare articles

| | |
|---|---|
| DEHP | Di ethyl hexyl phthalate |
| BBP | Benzyl butyl phthalate |
| DBP | Di butyl phthalate |

Less than 0.1% in toys and childcare articles for children under 36 months which are intended to be placed in the mouth

| | |
|---|---|
| DOP | Di octyl phthalate |
| DINP | Di iso nonyl phthalate |
| DIDP | Di iso decyl phthalate |

# Testing for Phthalate Plasticisers

Four common methods:

- EN 15777
- EN 14372
- ISO TS 16181
- ISO 14389

All use solvent extraction or dissolution followed by GC-MS analysis

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# Alternatives to Banned Phthalate Plasticisers

- Remember, restrictions on phthalate plasticisers do not amount to a ban on PVC
- Non-restricted phthalates can still be used
- Other plasticiser types exist such as adipates, cyclohexane derivatives and inorganic plasticisers

# Organotin Compounds

- Can be used as PVC stabilisers and anti-Microbial treatments

- Residues from production processes (catalyst for PU)

- Anti-fouling compounds – original problems observed with marine life

# Organotin Compounds

- Measured as ppb level (parts per billion – µg/kg)
- Typical RSL requirements:

< 50ppb for tributyl tin (TBT)

< 200ppb for total organotins (DBT, MBT)

- Japan Law 112 (1973)
- Annex XVII entry number 20 (276/2010) applies to articles and has much higher levels

# Organotin Restrictions

Tri-butyl tin (TBT)
Tri-phenyl tin (TPhT)

Di-butyl tin (DBT)
Di-octyl tin (DOT)

All restricted to
< 0.1% (1000ppm)

Restricted since 01 July 2010

DBT restricted since Jan 2012
(Derogation on some products until 2015)

DOT restricted since Jan 2012 in specific items (including footwear)

# Organotin Compounds - testing

- SATRA TM 277
- EN ISO TS 16179

Ultrasonic extraction, derivation with sodium tetraethyl borate followed by GC-MS analysis

Also EN 71-3:2013 +A1:2014 limits for toys (<12 mg/kg organic tin in category III materials)

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# Regulation (EU) No 1272/2013

## Polycyclic Aromatic Hydrocarbons (PAHs)

- May be present in rubbers and plastics
- Possible contaminants in extender oils and carbon black pigment
- Restricted to < 1mg/kg where contact with skin or oral cavity since December 2015, (entry number 50)

# PAHs – Regulation (EU) No 1272/2013

Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs.

Such articles include amongst others:

— sport equipment such as bicycles, golf clubs, racquets

— household utensils, trolleys, walking frames

— tools for domestic use

— clothing, footwear, gloves and sportswear

— watch-straps, wrist-bands, masks, head-bands

# Annex XVII - Summary

- Requirements of Annex XVII were transposed from the old Marketing & Use Directive
- These requirements are mandatory for affected materials / mixtures
- Generally lower requirements than 0.1%
- Advisable to base restricted substances lists on these requirements

# Strategy To Demonstrate Restricted Substances Compliance

- Testing programme across product range
- Test products from different suppliers
- Cover large volume products first
- Learn from results
- Relationship with test laboratory(ies)

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# Suggested Testing Strategies

- Test for Annex XVII restricted substances and SVHCs separately

- Split into two groups for SVHC testing:
  - Basic: Relevant substances that might be present over 0.1%
  - Additional: Relevant substances unlikely to be present over 0.1%

# Suggested Testing Strategies

- Natural Textiles
- Synthetic Textiles
- Polymeric materials (plastics)
- Leather

# Natural Textiles - Restricted Substances

- Mandatory
  - Azo dyes
  - PCP

- Recommended
  - Formaldehyde

# Natural Textiles – SVHCs

- Basic testing
  - Metal screening
- Additional testing
  - Organic compounds GC-MS screening

# Synthetic Textiles - Restricted Substances

- Mandatory
  - Azo dyes
  - Organotins

- Recommended
  - Formaldehyde
  - Disperse Dyes

# Synthetic Textiles – SVHCs

- Basic testing
  - Metal screening
- Additional testing
  - Organic compounds GC-MS screening

# Polymers - Restricted Substances

- Mandatory
  - Cadmium & Lead?
  - Organotins
  - PAHs
- Recommended
  - Phthalates
  - Heavy Metals

# Polymers – SVHCs

- Basic testing
  - Phthalates (flexible polymers)
  - Metal screening (pigments/stabilisers)
  - DMFa (PU)

- Additional testing

  - Organic compounds GC-MS screening

# Leathers - Restricted Substances

- Mandatory
  - Azo dyes
  - PCP
  - Organotins
  - Chromium VI

- Recommended
  - Formaldehyde
  - Heavy Metals

# Leathers – SVHCs

- Basic testing
  - Metal screening and chromium VI (tanning salts)
  - Chlorinated paraffins
- Additional testing
  - Organic compounds GC-MS screening (solvent contaminants)

# Understanding Test Reports

- Who? - Accredited laboratory (ISO 17025)
- How? - Recognised methods (ISO,EN,BS, ASTM, SATRA) or
  Full description of procedure
- What? - Result
  - Units
  - Limit of detection
- When? - How recent was the testing?
- Requirement? - Pass/Fail

# Conversion of units

- 1 % = 10,000 ppm (parts per million)
- 0.1% = 1,000 ppm
- 0.01% = 100 ppm

- 1 mg/kg = 1 ppm
- 1 µg/kg = 1 ppb (parts per billion)
- 1 ppm = 1,000 ppb

# Analytical Techniques

- **GC-MS**

(Gas Chromatography – Mass Spectrometry)

- **ICP**

(Inductive Coupled Plasma) spectrometry

- **HPLC**

(High Performance Liquid Chromatography)

- **UV-Vis**

(UV/Visible Spectrometry)

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# Testing Summary

- It is commercially difficult to test every material for every substance
- Identify a programme which covers a range of products and formulations
- If raw materials change test again.

# Testing Summary

- Test most popular products first
- Possibility of combining samples for some tests
- Brand RSLs may require more demanding tests.

# Conclusions

- All consumer products supplied into EU (+EEA) will need to comply with substances in articles requirements of REACH
- Primary responsibility lies with the importer for goods manufactured outside of the EU
- Brands push request for information up the supply chain
- Testing may be required to demonstrate compliance

# REACH – The Future

- December 2016 – new SVHCs to be added?
- 2018 – Final registration dates for chemicals
- 2020 – ECHA target to complete SVHC List

# Questions and Answers

SATRA TECHNOLOGY

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# Thank-you for Listening